

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

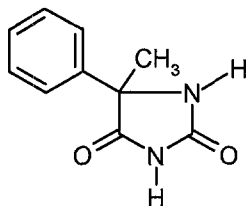
EPA MRID Number 45385824

Data Requirement: PMRA Data Code:
EPA DP Barcode:
OECD Data Point:
EPA Guideline: 163-1

Test material:

Common name: RPA 412636 (metabolite of fenamidone)
Chemical name
IUPAC: (S)-5-methyl-5-phenylimidazolidine-2,4-dione
CAS name: 2,4-Imidazolidinedione-5-methyl-5-phenyl-, (S)
CAS No: 27539-12-4
Synonyms: S-enantiomer of the racemic compound RPA 717879
SMILES string:

Chemical Structure:



Primary Reviewer: Dana Worcester
Dynamac Corporation

QC Reviewer: Joan Harlin
Dynamac Corporation

Secondary Reviewer: Silvia Termes
EPA

Company Code: [for PMRA]
Active Code: [for PMRA]
Use Site Category: [for PMRA]
EPA PC Code:

Signature:

Date:

Signature:

Date:

Signature:

Date:

*Signed by
Dynamac's
reviewers on
2/14/02*

26 Aug, 2002

CITATION: Burr, C.M. 1999. [¹⁴C]-RPA 412636 : Adsorption/desorption to and from four soils and a sediment. Unpublished study performed and sponsored by Rhône-Poulenc



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Signature: *Dana Worcester*
Date: 3/8/02

QC Reviewer: Joan Harlin
Dynamac Corporation

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Date: 3/8/02

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CITATION: Burr, C.M. 1999. [¹⁴C]-RPA 412636 : Adsorption/desorption to and from four soils and a sediment. Unpublished study performed and sponsored by Rhône-Poulenc Agriculture Ltd., Essex, UK. Laboratory Project ID. 14707. RPA Document 201866. Study initiated July 1, 1998 and completed February 3, 1999.

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Agriculture Ltd., Essex, UK. Laboratory Project ID. 14707. RPA Document 201866. Study initiated July 1, 1998 and completed February 3, 1999.

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PMRA Submission Number {.....}

EPA MRID Number 45385824

Administrative conclusions: This study conducted with the major metabolite of fenamidone (RPA 412636) is acceptable. The study provides mobility data for this metabolite. Together with the studies conducted with parent fenamidone and three other metabolites, it may be used to satisfy the 163-1 data requirement.. The requirement for a mobility study using parent fenamidone satisfied by MRID 45385823.

EXECUTIVE SUMMARY:

The adsorption/desorption characteristics of the fenamidone metabolite [phenyl-U-¹⁴C]RPA [(S)-5-methyl-5-phenylimidazolidine-2,4-dione] was studied in a silt loam soil [pH- 6.2, organic carbon - 0.5%] and sandy loam soil [pH - 6.7, organic carbon - 1.2%], each from the U.S., and a sandy clay loam sediment [pH - 8.2, organic carbon - 2.3%], silt loam soil [pH - 8.1, organic carbon - 1.9%], and loam soil [pH - 7.8, organic carbon - 2.0%], each from the UK, in a batch equilibrium experiment. The experiment was conducted in accordance with the U.S. EPA Pesticide Guidelines Subdivision N, 163-1 and OECD Guidelines for Testing of Chemicals, "Adsorption/Desorption", Guideline 106 (May, 1981), and in compliance with the GLP standard 40 CFR Part 160 and OECD-GLP. The adsorption phase of the study was carried out by equilibrating air-dried soil and sediment with RPA 412636 at nominal concentrations of 15.0, 3.0, 0.6, and 0.12 mg a.i./kg at 20 ± 1°C for 48 hours in the dark. The equilibrating solution used was 0.01 M CaCl₂, with soil/solution ratios of 1:3 (w:v) for all four soils and one sediment. The desorption phase of the study was carried out by replacing the adsorption solution with an equivalent volume of sterilized, pesticide-free 0.01 M CaCl₂ solution and equilibrating in the dark for 1 hour at 20°C. The desorption phase was repeated four times.

The supernatant solution after adsorption and desorption was separated by centrifugation and triplicate aliquots were analysed for total radioactivity using LSC. Following desorption, one sample of each soil and sediment was extracted and triplicate aliquots were analyzed by LSC. Radioactivity in the soil residue after the desorption or extraction step was determined by combustion. Aliquots (0.1-0.3 g) of soil were combusted and analyzed by LSC.

HPLC analysis of supernatants from the soil residues indicated that RPA 412636 was stable in the test solutions during the adsorption/desorption phase of the experiment. Supernatants analyzed by HPLC were from the highest treatment concentration. The mass balance was not reported at the end of adsorption phase of the study. The complete mass balance (adsorption and five desorption steps) was 99.8%, 98.8%, 99.4%, 99.8% and 97.8% of the applied in the Bosket silt loam soil, sandy loam soil, sandy clay loam sediment, Panholes silt loam soil, and loam soil, respectively.

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

After 48 hours of equilibration, 2.6-6.2%, 10.1-18.7%, 16.6-19.7%, 7.8-16.6%, and 11.9-25.5% of the applied RPA 412636 was adsorbed to the Bosket silt loam soil, sandy loam soil, sandy clay loam sediment, Panholes silt loam soil, and loam soil, respectively (reviewer-calculated). Freundlich K_{ads} values were 0.11, 0.43, 0.64, 0.32, and 0.56 for the silt loam soil, sandy loam soil, sediment, silt loam soil and loam soil, respectively. Corresponding adsorption K_{oc} values ranged from 17 to 36. At the end of the desorption phase, 93.4-97.2%, 86.0-93.0%, 91.1-94.7%, 82.1-92.0%, and 84.4-92.0% of the adsorbed amount was desorbed from the Bosket silt loam soil, sandy loam soil, sandy clay loam sediment, Panholes silt loam soil, and loam soil, respectively (reviewer-calculated). Following the final desorption step, Freundlich K_{des} values were 0.06, 62.27, 28.74, 16.12, and 12.89 for the Bosket silt loam soil, sandy loam soil, sandy clay loam sediment, Panholes silt loam soil, and loam soil, respectively; corresponding K_{oc} values ranged from 13 to 5189. Freundlich K_{des} and K_{oc} values were higher than those obtained for adsorption.

Results Synopsis: Adsorption and desorption values determined using Freundlich isotherm equations

Amounts adsorbed and desorbed were calculated by the reviewer.

Soil type: Bosket silt loam

Amount adsorbed: 2.6-6.2% of the applied

Adsorption K_{ads} : 0.11

Adsorption K_{oc} : 23

Amount desorbed: 93.4-97.2% of the adsorbed

Desorption K_d : 0.06

Desorption K_{oc} : 13

Soil type: Sandy loam

Amount adsorbed: 10.1-18.7% of the applied

Adsorption K_d : 0.43

Adsorption K_{oc} : 36

Amount desorbed: 86.0-93.0% of the adsorbed

Desorption K_d : 62.27

Desorption K_{oc} : 5189

Soil type: Sandy clay loam sediment

Amount adsorbed: 16.6-19.7% of the applied

Adsorption K_d : 0.64

Adsorption K_{oc} : 28

Amount desorbed: 91.1-94.7% of the adsorbed

Desorption K_d : 28.74

Desorption K_{oc} : 1249

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

Soil type: Panholes silt loam

Amount adsorbed: 7.8-16.6% of the applied

Adsorption K_d : 0.32

Adsorption K_{oc} : 17

Amount desorbed: 82.1-92.0% of the adsorbed

Desorption K_d : 16.12

Desorption K_{oc} : 848

Soil type: Loam

Amount adsorbed: 11.9-25.5% of the applied

Adsorption K_d : 0.56

Adsorption K_{oc} : 28

Amount desorbed: 84.4-92.0% of the adsorbed

Desorption K_d : 12.89

Desorption K_{oc} : 644

Study Acceptability: This study is classified supplemental. It is scientifically valid but cannot be used to satisfy the mobility data requirement because a fenamidone metabolite was studied rather than parent compound. The requirement for a mobility study using fenamidone is satisfied by MRID 45385823.

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study was conducted according to U.S. EPA Pesticide Assessment Guidelines Subdivision N, Series §163-1 (October 1982) and the EU Commission Directive 95/36/EC (July 1995). No deviations affected the validity of the study. Deviations from Subdivision N guidelines are:

The study was conducted using a metabolite rather than the parent compound.

COMPLIANCE: This study was conducted in compliance with 40 CFR Part 160, EPA GLP and OECD-GLP. Signed and dated GLP, Quality Assurance, Data Confidentiality, and Study Certification statements were provided.

A. MATERIALS:

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

1. Test Material RPA 412636 (metabolite of fenamidone)

Chemical Structure:

Description: Not reported

Purity: Analytical purity: Not provided Lot/Batch No.: Not provided
Radiochemical purity: >99% (p. 13)
Lot/Batch No.: CFQ 10605
Specific activity: 851 Mbq mmol
Locations of the label: Uniformly labeled in the phenyl ring

Storage conditions of test chemicals: Not provided

Physico-chemical properties of RPA 412636:

Parameter	Values	Comments
Water solubility	>10 mg/L	
Vapour pressure	Not provided	
UV absorption	Not provided	
pK _a	Not provided	
K _{ow}	Not provided	
Stability of Compound at room temperature	Not provided	

Data obtained from p. 14 of the study report.

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

2. Soil Characteristics

Table 1: Description of soil collection and storage.

Description	Silt loam	Sandy loam	Loam	Sandy clay loam	Silt loam
Geographic location	Leland, MS	Iola, Wisconsin	Essex, UK	Essex, UK	Kent, UK
Pesticide use history at the collection site	Not provided	Not provided	Not provided	Not provided	Not provided
Collection procedures	Not provided	Not provided	Not provided	Not provided	Not provided
Sampling depth (cm)	Not provided	Not provided	Not provided	Not provided	Not provided
Storage conditions	Not provided	Not provided	Not provided	Not provided	Not provided
Storage length	Not provided	Not provided	Not provided	Not provided	Not provided
Soil preparation	Sieved, 2 mm	Sieved, 2 mm	Sieved, 2 mm	Sieved, 2 mm	Sieved, 2 mm

Data were obtained from p. 14 of the study report.

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

Table 2: Properties of the soils.

Property	Bosket 96/19	Rosholt 96/44	Sediment 97/07	Panholes 97/10	Faulkbourne 98/09
Soil Texture	Silt loam	Sandy loam	Sandy clay loam	Silt loam	Loam
% sand	35.80	64.17	52.30	20.90	36.09
% silt	55.97	29.11	22.70	54.79	40.76
% clay	8.23	6.72	25.00	24.31	23.15
pH	6.2	6.7	8.2	8.1	7.8
Organic carbon (%)	0.5	1.2	2.3	1.9	2.0
CEC (meq/100 g)	5.7	6.5	63.6	65.7	10.0
Moisture at 1/3 atm (%)	25.41	20.66	30.00	25.86	21.00
Bulk density (lb/cu ft ³)	Not provided	Not provided	Not provided	Not provided	Not provided
Biomass (mg microbial C/100 g)	Not provided	Not provided	Not provided	Not provided	Not provided
Soil taxonomic classification	Fine-loamy, mixed, thermic mollic hapludalfs	Coarse-loamy, mixed typic glossoboralfs	Not provided	Fine-silty, mixed, mesic typic eutrochrept	Fine-loamy, mixed, mesic typic hapludalfs
Soil mapping unit (for EPA)	Not provided	Not provided	Not provided	Not provided	Not provided

Data obtained from Table 1, p. 30; Appendix 8, pp. 109-111 of the study report.

B. STUDY DESIGN:

1. Preliminary study: To determine whether the test substance adsorbed to glass tubes, 75 mL of a solution containing 1 mg/L of [¹⁴C]RPA 412636 in 0.01M CaCl₂ were added to two borosilicate screw-capped glass tubes externally coated with plastic, and the tubes were tightly capped and shaken on an end-over-end shaker in the dark at 20 ± 1°C for 24 hours (p. 15). Aliquots of the solutions were analyzed for total radioactivity using LSC. Results showed that RPA 412636 did not adsorb to the glass tubes; the mean recovery was 100.75% (99.4-102.1%; p. 22; Table 3, p. 31).

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

To determine the soil:solution ratio to be used in the definitive study, soil:solution ratios of 1:20, 1:5 and 1:3 were prepared by adding aliquots of a solution containing 1 mg/L of [^{14}C]RPA 412636 in 0.01M CaCl_2 to borosilicate screw-capped glass tubes containing 3, 15, and 20 g (dry weight equivalent) of each test soil and sediment (p. 15). The tubes were tightly capped, shaken by hand to suspend the soil, then shaken on an end-over-end shaker in the dark at $20 \pm 1^\circ\text{C}$ for 24 hours. The tubes were removed and centrifuged for 10 minutes at 2,000 rpm. Aliquots of the supernatants were analyzed for total radioactivity using LSC. Soil:solution ratios of 1:3 yielded recoveries of 64.3-82.7% of the applied in the supernatants (Table 4, p. 32). Soil:solution ratios of 1:5 and 1:20 yielded recoveries of 76.5-89.4% and 92.0-96.7% of the applied, respectively, in the supernatants.

To determine the equilibration time to be used in the definitive adsorption phase of the study, 60 mL of a 0.01M CaCl_2 solution containing [^{14}C]RPA 412636 were added to borosilicate screw-capped glass tubes containing 20 g (dry weight equivalent) of each test soil and sediment (p. 16). The tubes were shaken by hand to suspend the soil, then shaken on an end-over-end shaker in the dark at $20 \pm 1^\circ\text{C}$ for 1, 2, 4, 6, 24, 48, and 72 hours. The samples were centrifuged at 2,000 rpm for 10 minutes and triplicate aliquots of the supernatants were analyzed for total radioactivity using LSC. Results showed an initial, rapid decrease in radioactivity in the supernatants, that was followed by a gradual decrease, then little change after 24 hours (p. 22; Figure 1, p. 49).

To determine the equilibration time to be used in the definitive desorption phase of the study, 60 mL of a 0.01M CaCl_2 solution containing [^{14}C]RPA 412636 were added to borosilicate screw-capped glass tubes containing 20 g (dry weight equivalent) of each test soil and sediment (p. 17). The tubes were tightly capped, shaken by hand to suspend the soil, then shaken on an end-over-end shaker in the dark at $20 \pm 1^\circ\text{C}$ for 24 hours. The samples were centrifuged and the supernatants were decanted and replaced with pesticide-free 0.01M CaCl_2 . The tubes were then placed in the dark at 20°C and shaken on an end-over-end shaker for 1, 2, 4, 6, and 24 hours (p. 18). The samples were centrifuged at 2,000 rpm for 10 minutes and triplicate aliquots of the supernatants were analyzed for total radioactivity using LSC. In the four test soils and one sediment, the amount of radioactivity in solution was similar between 1 hour and 6 hours (p. 22; Figure 2, p. 49).

To determine the solubility of RPA 412636, approximately 1.9 mg of RPA 412636 was weighed into a 100-mL volumetric flask and 100 mL of deionized water was added to the flask (Appendix 3, p. 84). The solution was mixed in an ultrasonic bath for approximately 24 hours at 20°C , then filtered ($0.45\ \mu\text{m}$); aliquots were analyzed using LSC. The solution was re-filtered ($0.1\ \mu\text{m}$) and the radioactivity was determined using LSC. The solubility of RPA 412636 was determined to be $>10\ \text{mg/L}$.

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

Based on the results of the preliminary studies, it was determined that no adsorption of the test substance occurred on the glass wall, and that the definitive study would be conducted using a soil:solution ratio of 1:3, an adsorption phase equilibration period of 48 hours, a desorption phase equilibration period of 1 hour, and a maximum solution concentration of 5 mg/L for each of the test soils and sediment (p. 22; Appendix 3, p. 84).

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

2. Definitive study experimental conditions:

Table 3: Study design for the adsorption phase.

Parameters		Bosket silt loam	Sandy loam	Clay sediment	Panholes silt loam	Loam
Condition of soil (air dried/fresh)		Air-dried	Air-dried	Air-dried	Air-dried	Air-dried
Have these soils been used for other laboratory studies ? (specify which)		Yes. MRIDs 45385823, 45385825, 45385826, 45385828	Yes. MRIDs 45385823, 45385825, 45385826	Yes. MRIDs 45385823	Yes. MRIDs 45385823, 45385825, 45385826, 45385828	Yes. MRIDs 45385823, 45385825, 45385826, 45385828
Soil (g/replicate)		20 g	20 g	20 g	20 g	20 g
Equilibrium solution used (name and concentration; eg: 0.01N CaCl ₂)		0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂
Control used (with salt solution only) (Yes/No)		No	No	No	No	No
Test material concentrations	Nominal application rates (mg/kg)	15.0, 3.0, 0.6, 0.12	15.0, 3.0, 0.6, 0.12	15.0, 3.0, 0.6, 0.12	15.0, 3.0, 0.6, 0.12	15.0, 3.0, 0.6, 0.12
	Analytically measured concentrations (mg/kg)	15.4, 3.2, 0.6, 0.13	15.5, 3.2, 0.6, 0.12	15.8, 3.2, 0.6, 0.12	16.8, 3.2, 0.7, 0.13	15.7, 3.3, 0.65, 0.13
Identity and concentration of co-solvent, if any (mg/mL)		Acetonitrile, 1.4	Acetonitrile, 1.4	Acetonitrile, 1.4	Acetonitrile, 1.4	Acetonitrile, 1.4
Soil:solution ratio		1:3	1:3	1:3	1:3	1:3
Initial pH of the equilibration solution, if provided		Not provided	Not provided	Not provided	Not provided	Not provided

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

Parameters		Basket silt loam	Sandy loam	Clay sediment	Panholes silt loam	Loam
No. of replications	Controls	0	0	0	0	0
	Treatments	2	2	2	2	2
Equilibration	Time (hours)	48	48	48	48	48
	Temperature (°C)	20 ± 1	20 ± 1	20 ± 1	20 ± 1	20 ± 1
	Darkness (Yes/No)	Yes	Yes	Yes	Yes	Yes
	Shaking method	End-over-end shaker	End-over-end shaker	End-over-end shaker	End-over-end shaker	End-over-end shaker
	Shaking time (hours)	48	48	48	48	48
Method of separation of supernatant (eg., centrifugation)		Centrifugation	Centrifugation	Centrifugation	Centrifugation	Centrifugation
Centrifugation	Speed (rpm)	2,000	2,000	2,000	2,000	2,000
	Duration (min)	ca. 10	ca. 10	ca. 10	ca. 10	ca. 10
	Method of separation of soil and solution	Decantation	Decantation	Decantation	Decantation	Decantation

Data were obtained from pp. 15, 19, and Table 5, p. 32 of the study report.

1 Reviewer-calculated by multiplying the concentration (nominal/measured) by the volume of CaCl₂ solution used and dividing that number by the amount of soil used in the system (5 mg/L x 60 mL = 300 mg/20 g soil = 15 mg/kg).

**Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA
412636 in soil**

PMRA Submission Number {.....}

EPA MRID Number 45385824

Table 4: Study design for the desorption phase.

Parameters		Bosket silt loam	Sandy loam	Clay sediment	Panholes silt loam	Loam
Were the soil residues from the adsorption phase used? If not, describe the method for adsorption using a separate adsorption Table		Yes	Yes	Yes	Yes	Yes
Amount of test material present in the adsorbed state/adsorbed amount (mg a.i./kg soil)*	15.0	0.36331	1.4950	2.5111	1.2552	1.7990
	3.0	0.1490	0.4107	0.5625	0.2601	0.5247
	0.6	0.02659	0.0898	0.1137	0.0866	0.1358
	0.12	0.00733	0.0216	0.0238	0.0220	0.0307
No. of desorption steps		5	5	5	5	5
Equilibration solution and quantity used per treatment for desorption (eg., 0.01M CaCl ₂)		0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂
Soil:solution ratio		1:3	1:3	1:3	1:3	1:3
Replications	Controls	0	0	0	0	0
	Treatments	2	2	2	2	2
Desorption equilibration	Time (hours)	1	1	1	1	1
	Temperature (°C)	20 ± 1	20 ± 1	20 ± 1	20 ± 1	20 ± 1
	Darkness	Yes	Yes	Yes	Yes	Yes

**Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA
412636 in soil**

PMRA Submission Number {.....}

EPA MRID Number 45385824

Parameters		Bosket silt loam	Sandy loam	Clay sediment	Panholes silt loam	Loam
	Shaking method	End-over-end shaker	End-over-end shaker	End-over-end shaker	End-over-end shaker	End-over-end shaker
	Shaking time (hours)	1	1	1	1	1
Centrifugation	Speed (rpm)	2,000	2,000	2,000	2,000	2,000
	Duration (min)	10	10	10	10	10
	Method of separation of soil and solution	Not reported	Not reported	Not reported	Not reported	Not reported
Second - fifth desorption	Indicate if the method is same as the first desorption step.	Same	Same	Same	Same	Same

Data were obtained from p. 19 of the study report.

* Means were reviewer-calculated using Excel and data obtained from Tables 8-12, pp. 34-35 of the study report.

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

3. Description of analytical procedures:

Extraction/clean up/concentration methods: Following the final desorption step, 75 mL of acetonitrile:water (50:50, v:v) was added to one tube from each test soil and sediment and the tube was shaken to resuspend the soil (p. 19). The tubes were shaken on a wrist action shaker for 20 minutes, centrifuged for 10 minutes, and the supernatants were removed (method unspecified).

Total ^{14}C measurement: Triplicate aliquots of the supernatants were analyzed for total radioactivity using LSC. Following the final desorption or extraction, the soil residues were air-dried, ground to a fine powder, and triplicate subsamples (0.1-0.3 g) were analyzed for total radioactivity by LSC following combustion (p. 20).

Non-extractable residues, if any: Not applicable.

Derivatization method, if used: A derivatization method was not employed in the study.

Identification and quantification of parent compound: Supernatants analyzed by HPLC were from the highest treatment concentration. Identification and quantification of the RPA 412636 were performed by HPLC using the following operating conditions: Kromasil KR 100 5C1 column (4.6 x 250 mm), mobile phase of (A) acetonitrile:water (20:80, v:v) and (B) acetonitrile:water (40:60, v:v) [percent A:B at 0 min. 100:0 (%), 5 min. 100:0 (%), 10 min. 0:100 (%), 15 min. 0:100 (%), 17 min. 100:0 (%)], flow rate 1 mL/minute, with radiometric and UV (254 nm) detection (p. 20). The identity of RPA 412636 was confirmed by chromatographic comparison of the HPLC retention time of an unlabelled reference standard.

Identification and quantification of transformation products, if appropriate: Identification and quantification of transformation products were not performed.

Detection limits (LOD, LOQ) for the parent compound: The limit of detection for LSC analysis of RPA 412636 was reported to be 0.0299 ng/g (Appendix 9, p. 113). The limit of detection for HPLC analysis of RPA 412636 was reported to be 0.003 µg/g. The limits of quantification for LSC and HPLC analysis was not reported.

Detection limits (LOD, LOQ) for the transformation products, if appropriate: Identification and quantification of transformation products were not performed.

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

II. RESULTS AND DISCUSSION

A. TEST CONDITIONS: The stability of the test substance in solution during the definitive study for the four test soils and one sediment was confirmed, based on the results of HPLC analysis (p. 25). Degradation was $\leq 0.3\%$ of the applied in all supernatants analyzed (Table 18, p. 45).

B. MASS BALANCE: The mass balance was not reported at the end of adsorption phase of the study. Mass balances were calculated by summing the total amount of RPA 412636 recovered in the adsorption and desorption solutions, the soil extracts, and unextracted soil residues. Mass balances were 99.8, 98.8, 99.4, 99.8, and 97.8% of the applied for the Bosket silt loam soil, sandy loam soil, sandy clay loam sediment, Panholes silt loam soil, and loam soil, respectively (Tables 19-23, pp. 46-47).

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

Table 5: Recovery of RPA 412636, expressed as percentage of applied radioactivity, in soil after adsorption/desorption (n = 8; mean \pm s.d.)¹.

Matrices	Bosket silt loam	Sandy loam	Sandy clay loam sediment	Panholes silt loam	Loam
At the end of the adsorption phase					
Supernatant solution	81.51 ± 0.9	73.00 ± 3.1	60.25 ± 1.1	71.58 ± 3.5	64.15 ± 4.3
Solid phase (total ¹⁴ C)	Not determined				
Adsorption total recovery	Not determined				
At the end of the desorption phase					
Supernatant solution ²	17.45 ± 0.5	22.71 ± 2.0	36.39 ± 1.2	24.55 ± 1.6	29.48 ± 1.3
Solid phase (extracted) ³	--	--	--	--	--
Non-extractable residues in soil, if measured ³	0.83 ± 0.3	3.01 ± 1.0	2.89 ± 0.6	3.93 ± 1.3	4.49 ± 1.2
Desorption total Recovery	Not determined				
Total recovery	99.8 ± 0.7	98.8 ± 1.0	99.4 ± 0.7	99.8 ± 1.2	97.8 ± 1.8

¹ Means and standard deviations were reviewer-calculated using Excel and data obtained from Tables 19-23, pp. 46-47 of the study report.

² Values represent cumulative radioactivity in desorption supernatants for all five desorption steps.

³ Single samples were extracted; the extracted and unextractable values for these samples are not included in the table. The respective extracted and unextractable values are 0.1% and 0.4% for the silt loam soil; 0.4% and 1.2% for the sandy loam soil; 0.4% and 1.6% for the sediment; 0.4% and 1.6% for the silt loam soil; and 0.3% and 2.1% for the loam soil.

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

Table 6: Concentration of RPA 412636 in the solid and liquid phases at the end of adsorption equilibration period (n = 2; mean ± s.d.).¹

Concentration (mg a.i./kg)	Bosket silt loam			Sandy loam			Sandy clay loam sediment		
	on soil (mg a.i./kg) ²	in solution (µg a.i./mL)	% adsorbed ³	on soil (mg a.i./kg) ²	in solution (µg a.i./mL)	% adsorbed ³	on soil (mg a.i./kg) ²	in solution (µg a.i./mL)	% adsorbed ³
15.0	0.3633 ± 0.0	4.8822 ± 0.0	2.6 ± 0.2	1.4950 ± 0.0	4.4843 ± 0.0	10.1 ± 0.1	2.5111 ± 0.0	4.2844 ± 0.0	16.6 ± 0.1
3.0	0.1490 ± 0.0	0.9788 ± 0.0	4.9 ± 0.9	0.41066 ± 0.0	0.8838 ± 0.0	13.4 ± 0.4	0.56252 ± 0.0	0.8500 ± 0.0	18.3 ± 0.4
0.6	0.0266 ± 0.0	0.1908 ± 0.0	4.5 ± 0.6	0.08978 ± 0.0	0.1648 ± 0.0	16.6 ± 0.3	0.11372 ± 0.0	0.1641 ± 0.0	19.1 ± 0.5
0.12	0.0073 ± 0.0	0.0386 ± 0.0	6.2 ± 0.6	0.0216 ± 0.0	0.0329 ± 0.0	18.7 ± 1.2	0.02376 ± 0.0	0.0326 ± 0.0	19.7 ± 0.4

Concentration (mg a.i./kg)	Panholes silt loam			Loam		
	on soil (mg a.i./kg) ²	in solution (µg a.i./mL)	% adsorbed ³	on soil (mg a.i./kg) ²	in solution (µg a.i./mL)	% adsorbed ³
15.0	1.2552 ± 0.1	4.8086 ± 0.0	7.8 ± 0.2	1.7990 ± 0.0	4.4007 ± 0.0	11.9 ± 0.1
3.0	0.26001 ± 0.0	0.9156 ± 0.0	8.5 ± 0.0	0.52466 ± 0.0	0.8627 ± 0.0	17.0 ± 0.2
0.6	0.0867 ± 0.0	0.1834 ± 0.0	14.2 ± 0.0	0.13584 ± 0.0	0.1615 ± 0.0	21.7 ± 0.1
0.12	0.0220 ± 0.0	0.0357 ± 0.0	16.6 ± 0.6	0.03069 ± 0.0	0.0313 ± 0.0	25.5 ± 0.5

¹ Means and standard deviations were reviewer-calculated using Excel and data obtained from Tables 8-12, pp. 34-35; Appendix 5, pp. 86-98; and Appendix 6, pp. 97-98 of the study report.

² Reviewer-calculated by dividing soil concentration by treatment rate (0.372 µg/g x 21.3 g soil ÷ 282.209 µg = 2.8%)

³ The amount adsorbed was calculated by the reviewer as the difference between the amount applied and the amount in the aqueous phase.

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

Table 7: Concentration of RPA 412636 in the solid and liquid phases at the end of desorption (n = 2; total of all desorption phases).^{1,2}

Concentration (mg a.i./kg)	Bosket silt loam			Sandy loam			Sandy clay loam sediment		
	on soil (mg a.i./kg)	in solution (µg a.i./mL)	% desorbed as % of the adsorbed ³	on soil (mg/kg)	in solution (µg a.i./mL)	% desorbed as % of the adsorbed ³	on soil (mg/kg)	in solution (µg a.i./mL)	% desorbed as % of the adsorbed ³
15.0	0.006	0.808	97.2	0.3547	0.9874	93.0	0.4819	1.7594	94.7
3.0	0.057	0.168	96.6	0.1115	0.2203	90.4	0.1110	0.3656	93.5
0.6	0.007	0.035	95.7	0.0236	0.0453	87.8	0.0166	0.0740	92.8
0.12	0.002	0.007	93.4	0.0064	0.0101	86.0	0.0041	0.0149	91.1

Concentration (mg a.i./kg)	Panholes silt loam			Loam		
	on soil (mg/kg)	in solution (µg a.i./mL)	% desorbed as % of the adsorbed ³	on soil (mg/kg)	in solution (µg a.i./mL)	% desorbed as % of the adsorbed ³
15.0	0.3652	1.4867	92.0	0.353	1.3931	92.0
3.0	0.0417	0.2455	89.2	0.1515	0.3028	88.5
0.6	0.0295	0.0541	86.0	0.0509	0.0611	86.1
0.12	0.0092	0.0109	82.1	0.012	0.0126	84.4

¹ Means were reviewer-calculated using Excel and data obtained from Tables 13-17, pp. 36-44 of the study report.

² Each value in the solid phase is the amount present after the final desorption and each value in the solution phase is the total amount desorbed. Total amount in solution during the 3-5 desorptions was reviewer-calculated by summing amount in solution at each desorption 0.68919+0.105+0.0189.

³ The % desorbed as % of the adsorbed for each sample was calculated by the reviewer as follows: [% desorbed (desorption 1 + desorption 2 + desorption 3 + desorption 4 + desorption 5)] ÷ (% total recovery - % adsorbed); e.g., 100.5 - 82.7 = 17.8; 14.6 + 2.2 + 0.4 + 0.1 = 17.3; (17.3 ÷ 17.8) x 100= 97.2%.

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

Table 8: Freundlich adsorption and desorption constants of RPA 412636 in the soils.¹

Soil	Adsorption				Desorption ²			
	K	1/N	R ²	K _{oc}	K _d	1/N	R ²	K _{oc}
Bosket silt loam	0.11	0.832	0.988	23	0.06	0.333	0.225	13
Sandy loam	0.43	0.867	0.999	36	62.27	1.071	0.999	5189
Sandy clay loam sediment	0.64	0.957	1.000	28	28.74	1.072	0.997	1249
Bosket silt loam	0.32	0.811	0.996	17	16.12	0.894	0.912	848
Loam	0.56	0.821	0.998	28	12.89	0.838	0.992	644

¹ Data were obtained from Tables 6-7, p. 33 of the study report.

² Desorption values following the fifth desorption step.

K - Freundlich adsorption and desorption coefficients; 1/N - Slope of Freundlich adsorption/desorption isotherms.

K_{oc} - Coefficient adsorption per organic carbon (K_d or K x 100/% organic carbon).

R² - Regression coefficient of Freundlich equation.

C. ADSORPTION: After 48 hours of equilibration, 2.6-6.2%, 10.1-18.7%, 16.6-19.7%, 7.8-16.6%, and 11.9-25.5% of the applied RPA 412636 was adsorbed from the Bosket silt loam soil, sandy loam soil, sandy clay loam sediment, Panholes silt loam soil, and loam soil, respectively (reviewer-calculated). Freundlich K_{ads} values were 0.11, 0.43, 0.64, 0.32, and 0.56 for the Bosket silt loam soil, sandy loam soil, sandy clay loam sediment, Panholes silt loam soil, and loam soil, respectively; corresponding adsorption K_{oc} values were 23, 36, 28, 17, and 28 (Table 6, p. 33).

D. DESORPTION: At the end of desorption, 93.4-97.2%, 86.0-93.0%, 91.1-94.7%, 82.1-92.0%, and 84.4-92.0% of the adsorbed ¹⁴C was desorbed from the Bosket silt loam soil, sandy loam soil, sandy clay loam sediment, Panholes silt loam soil, and loam soil, respectively (reviewer-calculated). Following the last desorption step, Freundlich K_{des} values were 0.06, 62.27, 28.74, 16.12, and 12.89 for the Bosket silt loam soil, sandy loam soil, sandy clay loam sediment, Panholes silt loam soil and loam soil, respectively; corresponding desorption K_{oc} values were 13, 5189, 1249, 848, and 644 (Table 7, p. 33).

III. STUDY DEFICIENCIES: The objective of this study was to study the sorptive behaviour of the fenamidone metabolite RPA 412636 in four soils and one sediment with varying soil characteristics. None of the study deficiencies noted are considered to be of sufficient concern to cause the study to be judged scientifically invalid. However, since a metabolite of fenamidone was studied rather than the parent compound, this study cannot be used to fulfill Subdivision N

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

Guideline §163-1. This study does provide useful supplemental information on the mobility of RPA 412636 in four soils and a sediment.

IV. REVIEWER'S COMMENTS:

1. The Panholes silt loam and loam soils and the sandy clay loam sediment were foreign in origin. However, these soils and sediment were characterized according to the USDA soil textural classification system and were comparable to soils found in the United States.
2. The $1/n$ values associated with the Freundlich K_{ads} values for the four test soils were below 0.9; $1/n$ values associated with the Freundlich K_{ads} were 0.811-0.867; for the sediment, the Freundlich K_{ads} value was 0.957 (study report Table 6, p. 33). If the $1/n$ value is not within the range of 0.9 to 1.1, then the Freundlich isotherm may not adequately or accurately represent the adsorption of the compound across all concentrations.
3. RPA 412636 was moderately adsorbed to the test soils and sediment. The study author noted that for the four test soils, the relationship between test concentration and adsorption was non-linear, whereas for the sediment, increased test concentration resulted in increased adsorption (p. 26). RPA 412636 was less readily desorbed once it adsorbed to a test soil or sediment. The study author predicted that in the field, RPA 412636 movement could be less at lower concentrations than predicted using the adsorption isotherms. Similar behavior was noted for the mobility of fenamidone and other fenamidone transformation products (reviews included in this submission).
4. The amount of RPA 412636 (μg) adsorbed to the soils and sediment was calculated as the difference between the amount applied and the amount in the supernatant solution.
5. Silt loam desorption coefficients were calculated using the first desorption step because the correlation coefficients for the second and third desorption steps were low (<0.7), and because no radioactivity remained adsorbed to the soil at the end of third desorption (p. 25).
6. Sample storage intervals and conditions were not reported. Based on study report Table 2, the adsorption and desorption supernatants were stored for up to 5 days prior to HPLC analysis (p. 31).
7. Control samples were not employed in the definitive study.

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 412636 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385824

8. Method detection limits were not reported. Both method detection limits and limits of quantitation should be reported to allow the reviewer to evaluate the adequacy of the method.

V. REFERENCES: The following references were cited in the study:

United States Environmental Protection Agency Pesticide Assessment Guidelines, Subdivision N, October 18, 1982.

EU Commission Directive 95/36/EC July 1995, amending Council Directive 91/414/EEC.

OECD Method 106, Paris 1981.

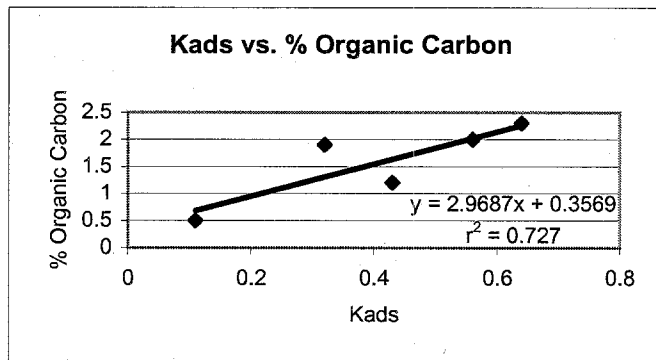
McCall, P.J., R.L. Swann, D.A. Laskowski, S.M. Unger, S.A. Vrona, and H.J. Dishburger. 1980. *Bull. Environ Contam. Toxicol.* 24, pp. 190-195.

Attachment 1
Excel Spreadsheets

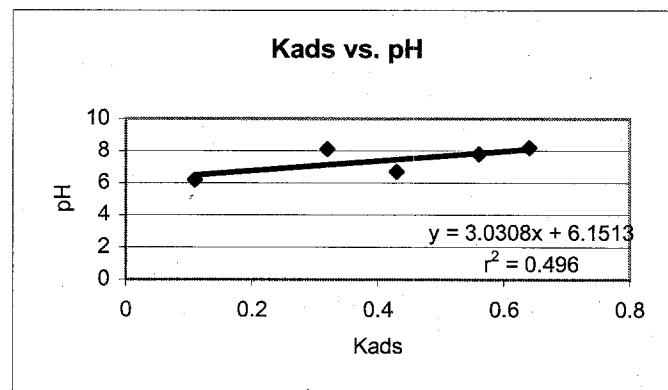
Chemical Name
MRID
Guideline No.

Fenamidone Metabolite RPA 412636
45385824
163-1

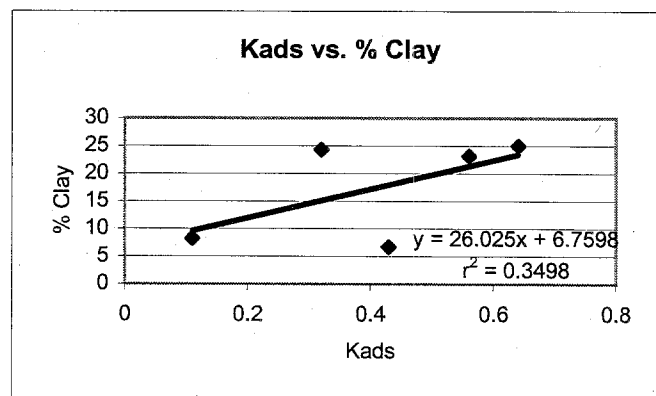
Soil	Kads	% Organic Carbon
Silt loam	0.11	0.5
Sandy loam	0.43	1.2
Sediment	0.64	2.3
Silt loam	0.32	1.9
Loam	0.56	2



Soil	Kads	pH
Silt loam	0.11	6.2
Sandy loam	0.43	6.7
Sediment	0.64	8.2
Silt loam	0.32	8.1
Loam	0.56	7.8



Soil	Kads	% Clay
Silt loam	0.11	8.23
Sandy loam	0.43	6.72
Sediment	0.64	25
Silt loam	0.32	24.31
Loam	0.56	23.15



Fenamidone Metabolite RPA 412636
163-1
MRID 45385824

Table 4/6

Adsorbed		Silt loam	Sandy loam	Sediment	Silt loam	Loam
	5	0.37166	1.50186	2.52974	1.29671	1.78311
	5	0.35495	1.4882	2.49236	1.21371	1.81479
average		0.363305	1.49503	2.51105	1.25521	1.79895
s.d.		0.011816	0.00965908	0.026432	0.05869	0.022401
	1	0.16874	0.41694	0.56873	0.26	0.52041
	1	0.12926	0.40438	0.55632	0.26011	0.5289
average		0.149	0.41066	0.562525	0.260055	0.524655
s.d.		0.027917	0.00888126	0.008775	7.78E-05	0.006003
	0.2	0.02414	0.09204	0.11197	0.08643	0.13589
	0.2	0.02903	0.08752	0.11546	0.08686	0.13578
average		0.026585	0.08978	0.113715	0.086645	0.135835
s.d.		0.003458	0.00319612	0.002468	0.000304	7.78E-05
	0.04	0.00786	0.02256	0.02315	0.02183	0.03065
	0.04	0.00679	0.02064	0.02437	0.02208	0.03072
average		0.007325	0.0216	0.02376	0.021955	0.030685
s.d.		0.000757	0.00135765	0.000863	0.000177	4.95E-05

Table 5

% Ads. Supernatant		Silt loam	Sandy loam	Sediment	Silt loam	Loam
	5	82.7	76.9	61.8	75.4	69.9
	5	83	76.9	61.7	75.1	69.8
	1	81.2	74.3	61.2	74.5	65.1
	1	81.6	75	59.3	74.2	65.9
	0.2	81.5	70.4	60.1	68.3	62.6
	0.2	80.9	70.6	59.3	68.8	62.1
	0.04	80.6	68.9	59.4	67.6	59.4
	0.04	80.6	71	59.2	68.7	58.4
average		81.5125	73	60.25	71.575	64.15
s.d.		0.907803	3.14960315	1.137667	3.484558	4.328972

Table 5

Des. 5 Supernatant		Silt loam	Sandy loam	Sediment	Silt loam	Loam
	5	17.3	20.7	34.8	22.3	27.8
	5	17.1	20.7	35.2	22.7	27.7
	1	16.6	21.8	35	24	30
	1	17.2	21.4	37	24.5	29
	0.2	18	24.7	37.1	26.8	29.3
	0.2	17.9	25.5	37.7	26.5	29.7
	0.04	17.8	24.2	37.2	25.1	30.9
	0.04	17.7	25	37.1	24.5	31.4
average		17.45	22.7142857	36.3875	24.55	29.475
s.d.		0.48107	2.04100815	1.172832	1.601785	1.324225

Table 5
Combusted

	Silt loam	Sandy loam	Sediment	Silt loam	Loam
5					
5	0.5	1.5	2	2	2.4
1	0.6	2.1	2.5	3.1	3.9
1	0.6	2.4	2.5	2.9	3.8
0.2	0.8	3.6	2.9	4.5	4.9
0.2	0.8	3.5	3	4.4	4.8
0.04	1.1	3.8	3.5	5.6	5.5
0.04	1.4	4.2	3.8	5	6.1
average	0.828571	3.01428571	2.885714	3.928571	4.485714
s.d.	0.31997	1.00900706	0.620292	1.28804	1.229402

Table 5
Recovery

	Silt loam	Sandy loam	Sediment	Silt loam	Loam
5	100.5	99.2	98.6	99.6	100.1
5	100.6	99.1	98.8	99.8	99.9
1	98.4	98.3	98.8	101.6	99
1	99.4	98.8	98.7	101.5	98.7
0.2	100.3	98.7	100	99.5	96.8
0.2	99.6	99.5	100	99.6	96.4
0.04	99.5	96.9	100.1	98.4	95.7
0.04	99.7	100.2	100.1	98.3	95.9
average	99.75	98.8375	99.3875	99.7875	97.8125
s.d.	0.719126	0.96796916	0.712014	1.225255	1.809844

Table 6
Solution

	Silt loam	Sandy loam	Sediment	Silt loam	Loam
5	4.87751	4.48127	4.28017	4.80545	4.40119
5	4.8869	4.4874	4.28869	4.81167	4.40024
average	4.882205	4.484335	4.28443	4.80856	4.400715
s.d.	0.00664	0.00433456	0.006025	0.004398	0.000672
1	0.97355	0.88036	0.85373	0.91588	0.86074
1	0.984	0.88716	0.84635	0.91522	0.86464
average	0.978775	0.88376	0.85004	0.91555	0.86269
s.d.	0.007389	0.00480833	0.005218	0.000467	0.002758
0.2	0.19157	0.16423	0.16505	0.18304	0.16177
0.2	0.19002	0.16538	0.16306	0.18371	0.16122
average	0.190795	0.164805	0.164055	0.183375	0.161495
s.d.	0.001096	0.00081317	0.001407	0.000474	0.000389
0.04	0.03847	0.03285	0.03276	0.03547	0.03145
0.04	0.0388	0.03288	0.03251	0.03582	0.03115
average	0.038635	0.032865	0.032635	0.035645	0.0313
s.d.	0.000233	2.1213E-05	0.000177	0.000247	0.000212

Table 6

% adsorbed

		Silt loam	Sandy loam	Sediment	Silt loam	Loam
	5	2.636344	10.1569526	16.72816	7.928382	11.86117
	5	2.473893	10.0238808	16.52482	7.62558	11.94723
average		2.555119	10.0904167	16.62649	7.776981	11.9042
s.d.		0.11487	0.09409599	0.143783	0.214113	0.06086
	1	5.50659	13.7295251	18.05432	8.528485	17.11427
	1	4.281305	13.0943506	18.62771	8.539289	16.8249
average		4.893947	13.4119378	18.34102	8.533887	16.96958
s.d.		0.866407	0.44913615	0.405449	0.007639	0.204618
	0.2	4.116285	16.85136	18.73693	14.20197	21.63194
	0.2	4.92862	16.3399538	19.50475	14.1337	21.78963
average		4.522453	16.5956569	19.12084	14.16783	21.71079
s.d.		0.574408	0.36161879	0.54293	0.04827	0.111507
	0.04	6.568144	19.499788	19.40928	16.96876	25.11138
	0.04	5.782734	17.8495538	19.93355	16.18242	25.88727
average		6.175439	18.6746709	19.67142	16.57559	25.49932
s.d.		0.555369	1.16689185	0.370716	0.556028	0.548633

Table 7

On soil

		Silt loam	Sandy loam	Sediment	Silt loam	Loam
	5	0.006	0.35683	0.50689	0.38326	0.33598
	5	0.005	0.35252	0.45696	0.34722	0.36995
average		0.0055	0.354675	0.481925	0.36524	0.352965
s.d.		0.000707	0.00304763	0.035306	0.025484	0.02402
	1	0.074	0.11365	0.11331	0.04381	0.14536
	1	0.04	0.10931	0.10874	0.03955	0.15754
average		0.057	0.11148	0.111025	0.04168	0.15145
s.d.		0.024042	0.00306884	0.003231	0.003012	0.008613
	0.2	0.004	0.02613	0.01681	0.02982	0.05051
	0.2	0.009	0.02107	0.01647	0.02914	0.05135
average		0.0065	0.0236	0.01664	0.02948	0.05093
s.d.		0.003536	0.00357796	0.00024	0.000481	0.000594
	0.04	0.002	0.00816	0.00391	0.00929	0.01188
	0.04	0.002	0.00458	0.00426	0.00904	0.01206
average		0.002	0.00637	0.004085	0.009165	0.01197
s.d.		0	0.00253144	0.000247	0.000177	0.000127

Table 7

Total Solution

		Silt loam	Sandy loam	Sediment	Silt loam	Loam
	5	0.81309	0.96126	1.74998	1.69188	1.38903
	5	0.8034	1.01344	1.76875	1.28154	1.39718
average		0.808245	0.98735	1.759365	1.48671	1.393105
s.d.		0.006852	0.03689683	0.013272	0.290154	0.005763
	1	0.166	0.22115	0.36502	0.24436	0.30315
	1	0.169	0.2194	0.3662	0.24666	0.30252
average		0.1675	0.220275	0.36561	0.24551	0.302835
s.d.		0.002121	0.00123744	0.000834	0.001626	0.000445
	0.2	0.035	0.04485	0.07398	0.05361	0.06119
	0.2	0.035	0.04569	0.07409	0.05449	0.06105
average		0.035	0.04527	0.074035	0.05405	0.06112
s.d.		0	0.00059397	7.78E-05	0.000622	9.9E-05
	0.04	0.007	0.01049	0.01489	0.0108	0.01266
	0.04	0.007	0.0098	0.01494	0.01109	0.01249
average		0.007	0.010145	0.014915	0.010945	0.012575
s.d.		0	0.0004879	3.54E-05	0.000205	0.00012

Table 7

% desorb as % of adsorb

		Silt loam	Sandy loam	Sediment	Silt loam	Loam
	5	97.19101	92.8251121	94.56522	92.14876	92.05298
	5	97.15909	93.2432432	94.87871	91.90283	92.02658
average		97.17505	93.0341777	94.72196	92.0258	92.03978
s.d.		0.022571	0.29566336	0.22167	0.173896	0.018669
	1	96.51163	90.8333333	93.08511	88.56089	88.49558
	1	96.62921	89.9159664	93.90863	89.74359	88.41463
average		96.57042	90.3746499	93.49687	89.15224	88.4551
s.d.		0.083146	0.64867639	0.582319	0.836298	0.057234
	0.2	95.74468	87.2791519	92.98246	85.89744	85.67251
	0.2	95.72193	88.2352941	92.62899	86.03896	86.58892
average		95.7333	87.757223	92.80572	85.9682	86.13072
s.d.		0.016091	0.67609462	0.249936	0.100073	0.647997
	0.04	94.17989	86.4285714	91.40049	81.49351	85.12397
	0.04	92.67016	85.6164384	90.70905	82.77027	83.73333
average		93.42503	86.0225049	91.05477	82.13189	84.42865
s.d.		1.067545	0.5742648	0.488925	0.902808	0.983326

Attachment 2

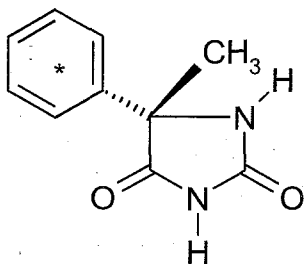
Structures of Parent and Transformation Products

RPA 412636

IUPAC name: (S)-5-Methyl-5-phenylimidazolidine-2,4-dione

CAS name: 2,4-Imidazolidinedione,5-methyl-5-phenyl-, (S)

CAS #: 27539-12-4



* Position of [^{14}C] radiolabel